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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,920	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61,71,72,74,77-79,81,85-89 and 91-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61, 71, 72, 74, 77-79, 81, 85-89 and 91-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are pending.

Claims 69, 70, 75, 76 and 80 have been cancelled.

Claims 61, 71, 77-79, 81, 85 and 87-89 have been amended.

Claims 91-93 have been added.

Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Grounds of Objection

Claim Objections

3. The objection of claim 70 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of the cancellation of the claim.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The ***NEW MATTER REJECTION of*** claims 61, 69-72, 74-81 and 85-89 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

5. The rejection of claim 61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to claim 61. Claims 81 and 87 have cancelled.

Claim Rejections - 35 USC § 102

6. The rejection of claims 61, 71, 72, 74, 81, 85 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Lanza et al. (British Journal of Haematology 77: 66-72, 1991) is withdrawn in light of Applicants' amendments to the claims. Claims 75 and 76 have been cancelled.

7. The rejection of claims 61, 71, 72, 74, 81 and 85 under 35 U.S.C. 102(b) as being anticipated by Guc et al. (Eur. J. Haematol 64(1): 3-9, January 2000) is withdrawn in light of Applicants' amendments to the claims. Claims 75 and 76 have been cancelled.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 87-89 and 93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claims are directed to methods of diagnosing breast cancer and carcinoma comprising contacting *a polynucleotide* that hybridizes under highly stringent conditions to *the complement* of a nucleic acid having the nucleotide sequence comprising of SEQ ID NO: 1320 with nucleic acids of a patient breast sample under binding conditions suitable to form a duplex and comparing the amount of the duplex formed to the amount of duplex formed when the polynucleotide is contacted with nucleic acids of a normal, non-cancerous breast control indicative of the presence of breast cancer or carcinoma in said patient. The written description is not commensurate in scope with these method claims drawn to a method of detection of a polynucleotide that hybridizes to a complement of a nucleic acid having the sequence of SEQ ID NO: 1320, which have not been adequately described nor evidenced to be in the possession of Applicants. Applicants seem to only be in possession of SEQ ID NO: 1320. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identify characteristics sufficient

to show that the applicant was in possession of the claimed invention", see Official Gazette, 1242 OG 172, January 30, 2001.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of nucleotide sequences short fragments and less than full complements of SEQ ID NO: 1320 and conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The product itself is required. Applicants have not fragments and complements of SEQ ID NO: 1320 with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written

description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 61, 71, 72, 74, 77-79, 81, 85, 91 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Qi et al. (Abstract from British Journal of Cancer

69(5): 903-910, 1994). Qi discloses the increased expression (82%) of cripto-1 (CR-1) in primary infiltrating ductal (IDCs) and infiltrating lobular breast carcinomas (ILCs) examined immunocytochemistry. However, of the 23 adjacent, non-involved breast tissue samples, CR-1 could be detected by ICC in only three (13%) of the samples. Absent evidence to the contrary the CR-1 described in Qi is the same as the CR1 corresponding to SEQ ID NO: 1320 in the claimed invention.

12. Claims 91 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Saeki et al. (Cancer Research 52: 3467-3473, June 15, 1992). Saeki discloses increased expression of cripto in human colorectal tumors in contrast to no expression of cripto in normal colon specimens, see abstract. Absent evidence to the contrary the cripto described in Saeki is the same as the CR1 corresponding to SEQ ID NO: 1320 in the claimed invention.

13. Claims 61, 71, 72, 74, 77-79, 81, 85, 86, 91 and 92 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003). The publication discloses diagnosing lung, colon and breast cancer with the assessment of cripto tumor polynucleotides and polypeptides via RT-PCR, see pages 23 and 24. Absent evidence to the contrary the cripto described in the publication is the same as the CR1 corresponding to SEQ ID NO: 1320 in the claimed invention.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qi et al. (Abstract from British Journal of Cancer 69(5): 903-910, 1994), and further in view of U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003) and U.S. Patent 6,852,506 B1 (filed April 11, 1997). The teaching of Qi have been presented in the 102(b) rejection. Qi does not teach the disclosed method wherein a polynucleotide from a patient sample that hybridizes under highly stringent conditions set forth in claims 87 and 93 forms a duplex and the duplex amount is compared to the amount of duplex in a non-cancerous breast control.

However, the publication teaches PCR amplification, which involve hybridization techniques. The patent teaches diagnostic assays for detecting altered levels of extracellular/epidermal growth factor (EEGF) polynucleotides and encoded polypeptides would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of the publication in order to effectively diagnose breast cancer using the methodology cited therein using the hybridization criteria set forth in the claims, see patent '506, columns 17 and 19. Cripto 1 is art known to be an EEGF. Furthermore, one of ordinary skill in the art would have

been motivated to do so with a reasonable expectation of success by the listed teachings in the patent application publication that the method implementing a range of washes and stringencies is routine in experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

16. Claims 61, 71, 72, 74, 77-79, 81, 85-89 and 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2004/0054142 A1 (effective filing date August 4, 2003), and further in view of U.S. Patent 6,852,506 B1 (filed April 11, 1997). The teaching of the patent application publication ave been presented in the 102(e) rejection. Publication '4142 does not teach the disclosed method wherein a polynucleotide from a patient sample that hybridizes under highly stringent conditions set forth in claims 87 and 93 forms a duplex and the duplex amount is compared to the amount of duplex in a non-cancerous breast control.

However, the publication teaches PCR amplification, which involve hybridization techniques. The patent teaches diagnostic assays for detecting altered levels of extracellular/epidermal growth factor (EEGF) polynucleotides and encoded polypeptides would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of the publication in order to effectively diagnose breast cancer using the methodology cited therein using the hybridization criteria set forth in the claims, see patent '506, columns 17 and 19. Cripto

1 is art known to be an EEGF. Furthermore, one of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the listed teachings in the patent application publication that the method implementing a range of washes and stringencies is routine in experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

Double Patenting

17. The provisional rejection of claims 61, 71, 72, 74, 77-79, 81 and 85-89 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 44 and 49 of copending Application No. 10/573,332 (filed April 6, 2007) is maintained. Claims 69, 70, 75, 76 and 80 have been cancelled.

Applicants have renewed their request this rejection be held in abeyance until an indication of allowable subject matter is indicated, see page 10 of the Remarks submitted of October 6, 2008. This point of view has been carefully considered and the rejection is maintained for the reason within and set forth previously in the Action mailed November 19, 2007.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be

reached Monday through Saturday between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
02 January 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643